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| APPLICATION NO.                                                                                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
|----------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------------------|-----------------------------|
| 10/525,011                                                                                         | 08/15/2005  | Jari Natunen         | 0933-0236PUS1                   | 1740                        |
| 2292 7590 01/14/2008<br>BIRCH STEWART KOLASCH & BIRCH<br>PO BOX 747<br>FALLS CHURCH, VA 22040-0747 |             |                      | EXAMINER<br>GODDARD, LAURA B    |                             |
|                                                                                                    |             |                      | ART UNIT<br>1642                | PAPER NUMBER                |
|                                                                                                    |             |                      | NOTIFICATION DATE<br>01/14/2008 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

## Office Action Summary

**Application No.**

10/525,011

**Applicant(s)**

NATUNEN ET AL.

**Examiner**

Laura B. Goddard, Ph.D.

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 87-135 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 87-135 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 87-104, 113, 120, 122-125, drawn to the special technical feature of a substance or antibody binding to a human tumor specific oligosaccharide sequence containing a terminal protein linked GlcNAc $\beta$ -structure or a terminal protein linked GlcNAc $\beta$ -glycan-structure.

Group II, claim(s) 105, drawn to the special technical feature of a method of making a medicament for the treatment of human cancer using a substance binding to a human tumor specific oligosaccharide sequence containing a terminal protein linked GlcNAc $\beta$ -structure or a terminal linked GlcNAc $\beta$ -glycan-structure.

Group III, claim(s) 106-112, drawn to the special technical feature of a method for diagnosing cancer or tumor in a biological sample taken from a human patient comprising determining the presence in said sample of an oligosaccharide sequence which comprises a tumor specific terminal protein linked GlcNAc $\beta$ -structure or terminal protein linked GlcNAc $\beta$ -glycan-structure.

Group IV, claim(s) 114, 118, 119, drawn to the special technical feature of an antigenic substance comprising a terminal protein linked GlcNAc $\beta$ -structure or terminal protein linked GlcNAc $\beta$ -glycan-structure in a chemically or biochemically synthesized polyvalent form.

Group V, claim(s) 115, drawn to the special technical feature of producing polyclonal or monoclonal antibodies using the antigenic substance of claim 114 or analogs or derivatives thereof.

Group VI, claim(s) 116, drawn to the special technical feature of purifying antibodies from human serum using the antigenic substance according to claim 114 or analogs or derivatives thereof.

Group VII, claim(s) 117, drawn to the special technical feature of detection and/or quantification of antibodies using the antigenic substance of claim 114 or analogs or derivatives thereof.

Group VIII, claim(s) 121, drawn to the special technical feature of a method for identifying cancer or tumor specific therapeutics or diagnostic agents comprising the steps of contacting a compound with a terminal protein linked GlcNAc $\beta$ -structure or terminal protein linked GlcNAc $\beta$ -glycan-structure and determining binding to said oligosaccharide.

Group IX, claim(s) 126-131, drawn to the special technical feature of treatment or diagnosis of cancer or tumor comprising transferring a modified monosaccharide derivative to cancer cells or tumor by a glycosyl transferase or a transglycosylate enzyme.

Group X, claim(s) 132-135, drawn to the special technical feature of a composition comprising an enzyme substrate, capable of being transferred specifically to a surface of a pathogenic entity or malignant cell or tissue by transferring enzyme making a covalent linkage between said enzyme substrate and an acceptor structure of said surface for use as a medicine.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-X appears to be a substance binding to a human oligosaccharide sequence containing a terminal protein linked GlcNAc $\beta$ -structure.

However, said technical feature does not constitute a special technical feature in view of Hanisch et al (Cancer Research, 1993, 53:4791-4796). Hanisch et al teach a monoclonal antibody 2B5 that binds a human oligosaccharide sequence containing a terminal protein linked GlcNAc $\beta$ -structure that is found in human gastric carcinoma (abstract; p. 4791 both columns; Table 2; p. 4795, col. 2).

Therefore, the technical feature linking the inventions of Groups I-X does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-X are not so linked by the same or a corresponding special technical feature as to form a single general incentive concept and restriction for examination purposes as indicated is proper.

**Note:**

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the

requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

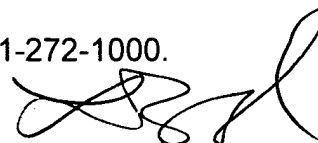
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Laura B Goddard, Ph.D.  
Examiner  
Art Unit 1642